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GROUP 1600

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/762,850

Filing Date: April 13, 2001

Appellant(s): ZIMMERMANN ET AL.

Mitchell D. Hirsch
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed Sept. 15, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

Art Unit: 1651

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of the invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: the rejection under 35 U.S.C. 112, first paragraph, is withdrawn.

(7) Grouping of Claims

The rejection of claims 29-42, 52 and 56 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c) (7).

(8) ClaimsAppealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Klock et al., Production of Purified Alginates Suitable For Use in Immunoisolated Transplantation, *Appl. Microbial Biotechnol.* (1994) 40: 638-643.

4,954,447 Nevins et al 9-1990

5,489,674 Yeh 2-1996

Zimmermann et al (DE 42 04 012 A1) is withdrawn as cumulative.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On further consideration, the second paragraph rejection is withdrawn except follows.

Art Unit: 1651

Dependent claims 30-32 are unclear by claims 30 and 32 not having clear antecedent basis for "the extraction" and claim 31 not having clear antecedent basis for "the extracting". Claim 29 does not now require extracting.

In line 2 of claim 30, "a" should be changed to --- the --- to be clear that the complexing agent is that of claim 29.

In claim 31, the meaning of "soda solution" is uncertain. This term is not defined in the specification, and it has not been established that it has a precise and definite art recognized meaning.

In line 2 of claim 34, "on the basis of" makes unclear the relationship of the porous granulate to the materials that are on the basis. The term should be replaced with --- formed from ---. Bridging lines 1 and 2 of the claim, "recycling materials from regenerated raw materials" is uncertain as to meaning and scope. The meaning of this limitation is not described in the specification, and material within and not within the scope of the limitation is uncertain.

Bridging lines 1 and 2 of claim 35, "deep filters" is unclear as to meaning and scope. The term is not defined in the specification, and it is uncertain as to filter structure that is deep and not deep.

(11) Response to Argument

Art Unit: 1651

In regard to claims 30-32, Appellants indicate (page 14, first paragraph of the brief) they are willing to amend the claims to recite "treating" (recited in claim 29) in place of "extracting" or "extraction".

Appellants assert (page 14, second paragraph) that "soda solution" in claim 31 means a solution containing sodium such as a Na_2CO_3 solution. However, there is inadequate support in the specification that "soda solution" is to encompass any sodium-containing solution such as a sodium hydroxide solution or a sodium chloride solution that is quite different from a Na_2CO_3 solution. Appellants indicate they are willing to amend the claim.

In regard to "on the basis of" in claim 34, appellants urge (page 14, third paragraph) that this term, while not being an ideal translation from the German original, will be understood in its context by one of ordinary skill in the art. However, if not an accurate translation, it is not seen how one will know the meaning and scope of the term in the claim. Appellants indicate they are willing to amend the claim.

Appellants urge (page 14, fourth paragraph) that "deep filters" in claim 35, while not being an ideal translation, will be understood from the specification (page 14, lines 6-9) as referring to ultrafiltration, or the use of filters having a

Art Unit: 1651

very small pore size. While the specification discloses the term "deep filter" and the filter having a pore size of 15 μm , the specification provides no description that the filter being "deep" is determined by its pore size. The term "deep" could relate to filter structure other than pore size, and it would be uncertain to the skilled artisan as to the structure that is "deep". Appellants indicate they are willing to amend the claim.

(12) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

Claims 29-42, 52 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klock et al (AP) in view of Nevins et al (4,954,447) and Yeh (5,489,674).

The claims are drawn to a process of obtaining a highly pure alginate composition. Claim 29 requires steps of (a) treating raw algae material with a complex forming agent creating a liquid comprising dissolved alginate and solid matter, (b) filtering the liquid to produce a filtrate containing dissolved alginate, (c) precipitating the alginate out of solution, (d) collecting and dewatering the precipitated alginate, and (e) repeating steps (a) to (d) at least once.

Art Unit: 1651

Klock et al disclose production of purified alginates suitable for use in immunoisolated transplantation by purifying raw alginates (page 640, right column, line 3, and line 9 of the second paragraph). The process exemplified (page 638 (abstract), paragraph bridging pages 639 and 640, and page 640, left column, beginning with the first full paragraph) involves dissolving commercial alginate (sodium alginate) in water, adding barium chloride to form barium alginate beads, extracting the beads, dissolving the beads in an alkaline EDTA solution to convert the barium alginate to sodium alginate, filtering the resultant solution, precipitating alginate and drying the precipitated alginate.

Nevins et al disclose (column 6, lines 32-35) that repeating purification steps when purifying an enzyme provides greater purity.

Yeh discloses (column 3, lines 58-62) that repeating process steps in purification of a polygalactomannan gum produces greater purity.

The steps of the process of Klock et al are encompassed by the present claims except that the claims require repeating the steps of the process at least once.

It would have been obvious to repeat the purification steps of Klock et al at least once to obtain greater purification as

Art Unit: 1651

suggested by Nevins et al and Yeh disclosing repeating purification steps of a process to obtain greater purity. When repeating the process steps of Klock et al as suggested by Nevins et al and Yeh, the resulting process is the same as required by claim 29. Treating barium alginate beads with alkaline EDTA (complex forming agent) to form soluble sodium alginate as disclosed by Klock et al (page 640, left column, 6th full paragraph) is encompassed by step a) of claim 29 since the barium alginate beads can be considered a "raw algae material" due to the beads not being the final purified product in the process of Klock et al. While the process of Klock et al reacts commercial sodium alginate with barium ion to form the barium alginate beads and then extracts the beads, the beads are still an impure form of alginate that must be further treated with alkaline EDTA to form soluble sodium alginate which is further treated by filtering, dialyzing, precipitating by ethanol and drying. Due to the several purification steps performed by Klock et al after forming the extracted barium alginate beads, the barium alginate beads are within the scope of "raw algae material". The present specification fails to contain a definition of "raw algae material" sufficiently limiting to exclude the raw algae material being the barium alginate beads of Klock et al. The specification provides examples of raw

Art Unit: 1651

algae materials the invention is "well-suited" (paragraph bridging pages 6 and 7), but makes no statement as to material the raw algae material cannot be. Commercial sodium alginate is a substantially purified form of algae material as compared to algae material as it exists in an algae plant since producing commercial sodium alginate involves isolating algae from the plant and treating it to form sodium alginate. If commercial sodium alginate, which is a processed algae material, can be considered a raw algae material because it is not a final purified product, it appears the barium alginate beads in the process of Klock et al can be considered a raw algae material, even though the beads result from further processing of commercial sodium alginate, since the beads are not the final purified product in the process of Klock et al. If the barium alginate beads of Klock et al were produced as a commercial alginate, and used as a starting material for the steps in Klock et al at page 640, left column, 6th complete paragraph, the barium alginate beads will clearly be a raw alginate material similar to commercial sodium alginate.

Steps b)-d) of claim 29 are steps performed in the process of Klock et al. Filtering as in step b), precipitating as in step c) and collecting and dewatering as in step d) are included in steps carried out by Klock et al (page 640, left column, 6th

Art Unit: 1651

complete paragraph). The final step of drying of Klock et al inherently dewatered.

The alginate composition of claim 52 resulting from the process of claim 29 will inherently be produced when carrying out the process of Klock et al and repeating the steps at least once for further purification as suggested by Nevins et al and Yeh. Moreover, appellants consider the dependent claims to stand or fall with claim 29 since page 5 of the brief designates claims 29-42, 52 and 56 as Group I, and states (line 3 from the bottom of the page) that none of the claims in this group are considered to be patentably distinct from one another.

(13) Response to Argument

In the brief on page 18, appellants present a table showing differences in the process of Klock et al and the process of claim 29. However, in the process of claim 29, step a) is treating "raw algae material", and this material encompasses the barium alginate beads produced in the process of Klock et al. Furthermore, claim 29, line 1, recites "comprising", and claim 29 does not exclude treating the beads and other steps that may be carried out by Klock et al that are not required in claim 29.

It is granted that Klock et al start with commercial alginate, as urged by appellants (page 19, second paragraph of the brief). However, after the commercial alginate is treated

Art Unit: 1651

to form barium alginate beads, the beads can still be a raw algae material since the beads must be further treated by purification steps to obtain the final purified product. As noted above, if the barium alginate beads of Klock et al were produced as a commercial alginate, and then used as a starting material for treating with EDTA and subsequent steps disclosed by Klock et al in the 6th paragraph in the left column on page 640, the barium alginate beads will be a raw algae material analogous to commercial sodium alginate. The instant specification indicates that the algae material or commercial alginate is a "source material" (page 7, line 20). The barium alginate beads of Klock et al are clearly a source material with respect to the step of treating the beads with alkaline EDTA and subsequent steps disclosed by Klock et al.

At page 20, last sentence of the second complete paragraph, appellants assert that the barium alginate beads of Klock et al are not raw algae material because the beads are the final purified product. However, this is not correct since Klock et al treat the beads (page 640, left column, 6th complete paragraph) with alkaline EDTA and other steps before the final purified product is produced. The beads having been treated by steps having a purifying function prior to treating with EDTA, does not make the beads the final purified product in the

Art Unit: 1651

process of Klock et al. While Klock et al may not refer to treatment with EDTA and subsequent steps as providing purification as urged by appellants, the steps inherently function to purify.

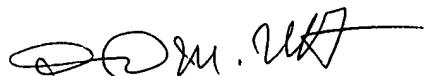
On page 22 of the brief, appellants urge that there is no motivation to combine the references. However, Nevins et al and Yeh clearly provide motivation to repeat steps of the process of Klock et al, e.g. to provide greater purity. The barium alginate beads of Klock et al are encompassed by the term "raw algae material" in claim 29 when the term is given its broadest reasonable interpretation.

A 37 CFR 1.132 Declaration of Dr. Frank Thurmer of 1/29/04 states (page 6, first paragraph, of the declaration) that the invention involves dissolving the alginate from plant cell walls by removing multivalent cations from the alginate with EDTA. However, the term "raw algae material" in claim 29 is not limited to plant material having cell walls containing alginate bound with multivalent cations.

For the above reasons, it is believed that the rejections should be sustained.

Art Unit: 1651

Respectfully submitted,



David M. Naff
Primary Examiner
Art Unit 1651

DMN

January 13, 2005

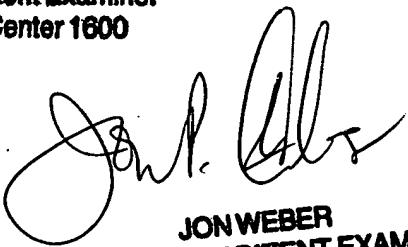
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